

<b>Case Number:</b>	CM15-0177913		
<b>Date Assigned:</b>	09/28/2015	<b>Date of Injury:</b>	01/11/2010
<b>Decision Date:</b>	11/20/2015	<b>UR Denial Date:</b>	08/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Emergency Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The 49 year old female injured worker suffered an industrial injury on 1-11-2010. The diagnoses included chronic pain, degeneration of the cervical disc and degeneration of the lumbar disc. On 8-3-2015 the treating provider reported neck and low back pain that radiated with numbness and tingling to the lower extremities. The pain was rated 9 to 10 out of 10 without medication and 6 to 7 out of 10 with medication. The provider noted she was able to fall asleep with the use of Lunesta and the provider reviewed sleep hygiene with the injured worker the provider noted no aberrant drug behavior, had an opiate contract and had a urine drug screen at the visit 8-3-2015 for screening purposes only. She had a lumbar epidural steroid injection with no lasting relief. She had physical therapy and home exercise with some benefit but still with radicular pain. On exam there was an altered gait with reduced lumbar range of motion, spasms, guarding and positive straight leg raise on the left. On 4-22-2015 the provider noted constipation however the visits 7-2-2015 and 8-3-2015 did not mention constipation or the effectiveness of the Senokot. She had been using Lunesta, Senokot, Gabapentin and Morphine since at least 4-22-2015. Prior treatment included lumbar epidural steroid injection, Functional Restoration Program and medication. Request for Authorization date was 8-5-2015. The Utilization Review on 8-12-2015 determined non-certification for Lunesta 2mg 1 tab QHS #30, Morphine sulfate CR 60mg 1 tab Q12H #60, Senokot-S 8.6/50mg 1 tab BID #60 x 3 refills and Gabapentin 600mg 2 tabs QD #6.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Lunesta 2mg 1 tab QHS #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Insomnia Treatment.

**Decision rationale:** The request is for the use of a medication used for insomnia. The Official Disability Guidelines state the following regarding this topic: Recommend that treatment be based on the etiology, with the medications recommended below. See also Insomnia. For more detail on Insomnia treatment, see the Mental Chapter. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. In this case, the use of this medication is not recommended. This is secondary to inadequate documentation of a thorough evaluation of the etiology or attempted non-pharmacologic restorative measures undertaken. As such, the request is not medically necessary.

**Morphine sulfate CR 60mg 1 tab Q12H #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement seen. As such, the request is not medically necessary, all opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Senokot-S 8.6/50mg 1 tab BID #60 x 3 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Opioid-induced constipation treatment.

**Decision rationale:** The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below; In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, and then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for non-cancer pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The patient is currently on a medication in the opioid class with the resultant side effect of constipation. The opioid medication is not medically necessary for use, As such; there is lack of need for this medication.

**Gabapentin 600mg 2 tabs QD #6:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement. As such, the request is not medically necessary.